

AMENDMENT TO THE CLAIMS

This listing of claims will replace all prior versions of claims in the application.

Listing of Claims:

1. (Original) A substantially pure nucleic acid molecule comprising: (i) a nucleic acid sequence encoding recombinant human alpha-fetoprotein (rHuAFP), (ii) a milk-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by milk-producing cells into the milk of a mammal.

2-5. (Cancelled)

6. (Currently Amended) Non-human mammal's milk comprising biologically active recombinant human alpha-fetoprotein (rHuAFP).

7. (Previously Presented) The milk of claim 6, wherein the rHuAFP is soluble and is produced by a non-human transgenic mammal whose genome comprises a transgene that effects expression of said rHuAFP in mammary epithelial cells of said mammal, wherein said transgene comprises: (i) a nucleic acid sequence encoding rHuAFP, (ii) a milk-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by said mammary epithelial cells into the milk of said mammal.

8-20. (Cancelled)

21. (Currently Amended) A non-human transgenic mammal that expresses biologically active recombinant human alpha-fetoprotein (rHuAFP) in its milk, wherein the genome of said mammal comprises a transgene that effects expression of rHuAFP in mammary epithelial cells of

said mammal, wherein said transgene comprises: (i) a nucleic acid sequence encoding rHuAFP, (ii) a milk-specific promoter, said promoter being operably linked to said rHuAFP-encoding sequence, and (iii) a leader sequence encoding a protein secretory signal that enables secretion of said rHuAFP by said mammary epithelial cells into the milk of said mammal.

22. (Previously Presented) The non-human transgenic mammal of claim 21, wherein the mammal is a goat, a cow, a sheep, or a pig.

23. (Currently Amended) A method for preparing biologically active recombinant human alpha-fetoprotein (rHuAFP) comprising the steps of:

- (a) providing the non-human transgenic mammal of claim 21; and
- (b) collecting milk containing said rHuAFP from said mammal.

24. (Previously Presented) The method of claim 23, further comprising step (c) purifying said rHuAFP from said milk.

25. (New) The nucleic acid molecule of claim 1, wherein said nucleic acid sequence is modified to express said rHuAFP in a non-glycosylated form.

26. (New) The milk of claim 7, wherein said transgene is modified to express said rHuAFP in a non-glycosylated form.

27. (New) The non-human transgenic mammal of claim 21, wherein said transgene is modified to express said rHuAFP in a non-glycosylated form.